Complete Summary

GUIDELINE TITLE

Depression following spinal cord injury. A clinical practice guideline for primary care physicians.

BIBLIOGRAPHIC SOURCE(S)

Depression following spinal cord injury. A clinical practice guideline for primary care physicians. Washington (DC): Paralyzed Veterans of America; 1998. 35 p. [112 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of January 2005, based on a review of literature published since the original guideline publication.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On July 1, 2005, in response to recent scientific publications that report the possibility of increased risk of suicidal behavior in adults treated with antidepressants, the U.S. Food and Drug Administration (FDA) issued a Public Health Advisory to update patients and healthcare providers with the latest information on this subject. Even before the publication of these recent reports, FDA had already begun the process of reviewing available data to determine whether there is an increased risk of suicidal behavior in adults taking antidepressants. The Agency has asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population taking antidepressants. This effort will involve hundreds of clinical trials and may take more than a year to complete. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Depression following spinal cord injury

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations on the general risk factors for depression; on the signs and symptoms of depression in people with spinal cord injury; and on the psychological, and social factors that cause or contribute to depression.

TARGET POPULATION

Individuals with spinal cord injury

INTERVENTIONS AND PRACTICES CONSIDERED

1. Routine screening for depression
2. Referral for psychotherapy when appropriate
3. Selection of appropriate psychopharmacological agents
4. Referral to a social worker, rehabilitation counselor, or case manager, as appropriate

5. Consumer and family education
6. Evaluation and modification of treatment plan

MAJOR OUTCOMES CONSIDERED

1. Symptomatic improvement with psychotherapy, pharmacotherapy, and/or electroconvulsive therapy for depression
2. Recurrence rates for depression
3. Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A comprehensive computer search of six database systems was completed for the year 1966 to 1998. The six databases were MEDLINE (U.S. National Library of Medicine), PsychLit, ERIC (Educational Resources Information Center), NARIC (National Rehabilitation Information Center), CINAHL (Cumulative Index to Nursing and Allied Health Literature), and Dissertation Abstracts. The search involved two general categories, spinal cord injury and depression. The keyword "depression" was cross-referenced with up to 14 related terms: psychological, psychosocial, adjustment, coping, counseling, family therapy, psycho-education, cognitive therapy, support groups, and behavior therapy. Because a few of the databases did not contain certain specific keywords used (e.g., in ERIC, the term "spinal cord injury" was not an available keyword so it was replaced with the broader term "disability").

All abstracts cited under these terms were screened. Articles were selected for this study based on four criteria: (1) the article had an experimental or quasi-experimental design with randomized assignment to group; 2) the article had an experimental or quasi-experimental design with no randomized assignment to group 3) The article was a case series with no controls; or 4) the article was a review though to have relevant information and citations. One hundred and fifteen articles were identified through this screening process. An additional eight articles were identified through peer recommendations.

NUMBER OF SOURCE DOCUMENTS

123 source documents

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Hierarchy of levels of scientific evidence:

I. Large randomized trial with definite results
II. Small randomized trials with uncertain results
III. Nonrandomized studies with concurrent controls
IV. Nonrandomized studies with historic controls
V. Case series with no controls

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

An evaluation tool was developed in part from:

1. Evaluation tools that currently exist (Kohn RL, Suydam MN. An instrument for evaluation survey research. J Educ Res 1970;64[2]:78-85; Thomas JP, Lawrence TS. Common deficiencies of NIDRR research applications. Am J Phys Med Rehabil 1991;70[1]:161-4),
2. A thorough review of credible statistics textbooks (Kirk RE. Experimental design: procedures for the behavioral sciences. Belmont [CA]: Brooks/Cole Publishing, 1982; Keppel G. Design and analysis: a researcher's handbook [2nd edition]. Englewood Cliffs [NJ]: Prentice-Hall, 1982; Stevens JP. On seeing the statistician, and some analysis caveats. Am j Phys Med Rehabil 1991;70:S151-2), and
3. Recently published articles identifying common deficiencies in research (Braddom CL. A framework for writing and/or evaluating research papers. Am J Phys Med Rehabil 1990;70[1]:1669-71; Dar R, Serlin RC, Omer H. Misuse of statistical tests in three decades of psychotherapy research. J Consult Clin Psychol 1994;62[1]:75-82; Ottenbacher K. Measures of effect size in the reporting of rehabilitation research. Am J Phys Med Rehabil 1990;69[2]:131-7; Thomas JP, Lawrence TS. Common deficiencies of NIDRR research applications. Am J Phys Med Rehabil 1991;70[1]:161-4).

The tool was divided into two broad sections, each containing separate criteria. Part one consisted of descriptive data, including variables that were investigated with depression, measures of depression, design of the study, retrieval form, and type of article. Part two consisted of 11 quantitative categories addressing a specific aspect of methodological standards: significance of problem or theoretical relevance, clarity of problem definition, scope of literature review, adequacy of the research design, control of variables, sample selection and sample size, psychomotor properties of the instruments, analysis techniques, interpretations and generalizations from the results, limitations of the study, and adequacy of the research report.

The methodologist, panel chairperson, and the Paralyzed Veterans of America staff identified a core field of approximately 33 key papers that covered the major issues in spinal cord injury. These articles were sent to panel members for study and consideration. During the subsequent period, the methodologist evaluated the articles and consulted with the panel chair and panel members. In addition,

another 30 articles were identified for evaluation for evaluation with respect to pharmacological interventions.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline development process adopted by the Spinal Cord Medicine Consortium consists of 12 steps, leading to panel consensus and organizational endorsement. After the steering committee chooses a topic, a panel of experts is selected. Panel members must have demonstrated leadership in the topic area through independent scientific investigation and publication. Following a detailed explication and specification of the topic by select steering committee and panel members, consultant methodologists review the international literature, prepare evidence tables that grade and rank the quality of research, and conduct statistical meta-analyses and other specialized studies, as needed. The panel chair then assigns specific sections of the topic to the panel members based on their area of expertise. Writing begins on each component using the references and other materials furnished by the methodology support group.

After the panel members complete their sections, a draft document is generated during the first full meeting of the panel. The panel incorporates new literature citations or other evidence-based information not previously available.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Categories of the Strength of Evidence Associated with the Recommendation:

A. The recommendation is supported by scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guidelines statement
B. The recommendation is supported by scientific evidence from properly designed and implemented clinical series that support the guidelines statement
C. The recommendation is supported by expert opinion

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The full document was reviewed by legal counsel, clinical expert from seventeen consortium organizations plus other select clinical experts and consumers. The review comments were assembled, analyzed and databased and the document was revised to reflect the reviewers' comments. Following a second legal review, the draft document was distributed to all consortium organization governing boards. Final technical details were negotiated among the panel chair, members of the organizations' boards, and expert panelists.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Assessment

1. Perform routine screening for depression during the individual's initial visit and annually thereafter. Self-report measures of depression may be helpful in screening psychological status, but should never be used without a clinical interview to establish the existence or absence of a depressive disorder.

   (Scientific evidence—III; Grade of recommendation—B; Strength of expert panel opinion—Strong)

2. Assess the individual for the presence of the following general risk factors for depression:
   - Prior episodes of depression
   - Family history of depressive disorder or bipolar disorder
   - Family history of suicide attempts
   - Current suicidal ideation
   - Age of onset under 40
   - Chronic pain
   - Female gender
   - Lack of social support
   - Postpartum
   - Multiplicity of life stressors
   - Concurrent medical illness
   - Concurrent substance abuse

   (Scientific evidence—IV; Grade of recommendation—C; Strength of expert panel opinion—Strong)

3. Assess individuals with spinal cord injury (SCI) for the specific risk factors of depression, including:
   - Complete neurologic injury
   - Medical comorbidity, including but not limited to traumatic brain injury (TBI)

   (Scientific evidence—V; Grade of recommendation—C; Strength of expert panel opinion—Strong)

4. Assess the individual for signs and symptoms of depression and potential for suicide during a history and physical examination.

(Scientific evidence—V; Grade of recommendation—C; Strength of expert panel opinion—Strong)

5. Identify the biological factors that may cause or contribute to depression, including the following physiological factors:
    - Biological effects of SCI, such as fatigue, anorexia, sleep disturbance, decreased energy
    - History of mood disorder
    - Family history of mood disorder
    - Presence of general medical condition that may cause or contribute to depression
    - Presence of medications or drugs that may cause or contribute to depression

    (Scientific evidence—IV; Grade of recommendation—C; Strength of expert panel opinion—Strong)

6. Conduct a comprehensive assessment of the social factors specific to spinal cord injury that contribute to depression to evaluate the adequacy of the individual's social support system in meeting basic needs and to determine the presence of depression in response to an inadequate support network. Specifically, the assessment should include but not be limited to:
    - The individual's social network, including family members, friends, and community organizations
    - The individual's financial resources
    - Vocational and avocational interests and issues
    - Current living arrangements, including wheelchair accessibility
    - Adaptive equipment needs and resources
    - Personal assistance needs and resources
    - Transportation needs and resources

    (Scientific evidence—II; Grade of recommendation—B; Strength of expert panel opinion—Strong)

7. Assess the psychological factors specific to spinal cord injury that contribute to depression, including the following:
    - Coping style
    - Self-blame for the injury
    - Unresolved conflicts from previous losses or traumas
    - Preinjury psychological or psychiatric impairment
    - Cognitive style
    - Grief and bereavement from SCI

    (Scientific evidence—V; Grade of recommendation—C; Strength of expert panel opinion—Strong)

Diagnosis

8. Use established diagnostic criteria to diagnose depression.

(Scientific evidence V; Grade of recommendation—C; Strength of expert panel opinion—Strong)

9. Identify the mental health factors that indicate referral to the appropriate mental health provider including:
    - Active suicidal ideation
    - Psychotic depression
    - Bipolar disorder
    - Complex psychiatric diagnoses such as depression that are associated with post traumatic stress disorder, obsessive-compulsive disorder, eating disorder, schizophrenia, schizophreniform disorder, schizoaffective disorder, and personality disorders
    - Persistent substance abuse complicating the diagnosis and/or management of depression (especially when detoxification or more intensive treatment beyond a 12-step program is needed)

    (Scientific evidence—V; Grade of Recommendation—C; Strength of expert panel opinion—Strong)

Treatment

10. Formulate a treatment plan identifying:
    - Which treatments are to be provided by the primary care physician
    - What type of individual and family education needs to be provided and by whom
    - Who will address comorbid conditions and how those conditions will be treated
    - Specific criteria for referring the individual to a mental health provider

    (Scientific evidence-IV; Grade of recommendation—C; Strength of expert panel opinion—Strong)

11. Provide or refer for psychotherapy by matching the type of psychological intervention to both the identified problem and the therapeutic capacity of the individual.

    (Scientific evidence—IV; Grade of recommendation—C; Strength of expert panel opinion—Strong)

Psychopharmacological Agents

12. If indicated, select appropriate antidepressant medications. Psychopharmacological agents should be considered for individuals who present significant biological, somatic, and/or mood-related symptoms of sufficient severity to disrupt the person's life and activities of daily living. Selection of a specific agent should be predicated upon the unique characteristics of the individual and the presenting signs and symptoms of depression.

    (Scientific evidence—I; Grade of recommendation—A; Strength of expert panel opinion—Strong)

Environmental and Social Factors and Social Support System

13. Address environmental and social factors and refer to a social worker, rehabilitation counselor, or case manager, as appropriate. When problems in the individual's support system are identified, treatment interventions should be implemented to strengthen the social support system. These interventions should be directed at one or more of the following areas:
    - Education and information regarding available resources
    - Referrals to existing community resources
    - Development of alternative to access services or assistance where no existing community resource is readily available
    - Advocacy to change public policy to ensure that individuals with SCI have the resources to meet their lifelong needs

    (Scientific evidence—V; Grade of recommendation C; Strength of expert panel opinion—Strong)

14. Provide patient and family education on the following topics:
    - Signs and symptoms of depression
    - Treatment options
    - Medications, side effects, adverse reactions, and drug interactions
    - Effect of depression on individuals with SCI/D
    - Effect of depression on the family
    - Community resources

    (Scientific evidence—V; Grade of recommendation—C; Strength of expert panel opinion—Strong)

Evaluation and Modification of Treatment Plan

15. Evaluate treatment, focusing on the following elements:
    - Evaluation of treatment efficacy
    - Modification of treatment, as indicated
    - Follow-up with referral sources

    (Scientific evidence—V; Grade of recommendation—C; Strength of expert panel opinion—Strong)

Definitions

Hierarchy of levels of scientific evidence:

I. Large randomized trial with definite results
II. Small randomized trials with uncertain results
III. Nonrandomized studies with concurrent controls
IV. Nonrandomized studies with historic controls
V. Case series with no controls

Categories of the Strength of Evidence Associated with the Recommendation:

A. The recommendation is supported by scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guidelines statement
B. The recommendation is supported by scientific evidence from properly designed and implemented clinical series that support the guidelines statement
C. The recommendation is supported by expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of scientific evidence and the grade of the recommendation are identified with each recommendation (see "Major Recommendations").

Of the 15 major recommendations, one was based on large randomized trials with definite results; one was based on small randomized trials with uncertain results; one was based on nonrandomized studies with concurrent controls; four were based on nonrandomized studies with historic controls; and eight were based on case series with no controls.

One recommendation was supported category A evidence, scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guidelines statement.

Three recommendations were supported by category B scientific evidence or evidence from properly designed and implemented clinical series that support the guidelines statement.

Eleven recommendations were supported by category C evidence or expert opinion.

All recommendations had strong expert panel agreement and support.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The benefits of clinical practice guidelines for the spinal cord medicine practice community are numerous. Among the more significant applications and results are the following:

- Clinical practice options and care standards
- Medical and health professional education and training
- Building blocks for pathways and algorithms
- Evaluation studies of guideline use and outcomes

- Research gap identification
- Cost and policy studies for improved quantification
- Primary source for consumer information and public education
- Knowledge base for improved professional consensus building

POTENTIAL HARMS

Side effect profiles of psychopharmacological agents.

Subgroups Most Likely to be Harmed:

Special consideration should be given when using antidepressants in the elderly and in individuals with hepatic or renal insufficiency and central nervous system compromise [traumatic brain injury (TBI), dementia, etc.].

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guide has been prepared based on scientific and professional information known about depression following spinal cord injury/dysfunction, its causes, and its treatments, in 1998. Users of this guide should periodically review this material to ensure that the advice herein is consistent with current reasonable clinical practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Depression following spinal cord injury. A clinical practice guideline for primary care physicians. Washington (DC): Paralyzed Veterans of America; 1998. 35 p. [112 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 (reviewed 2005)

GUIDELINE DEVELOPER(S)

Consortium for Spinal Cord Medicine - Private Nonprofit Organization
Paralyzed Veterans of America - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Consortium member organizations include: American Academy of Orthopedic Surgeons, American Academy of Physical medicine and Rehabilitation, American Association of Neurological Surgeons, American Association of Spinal Cord Injury Nurses, American Association of Spinal Cord Injury Psychologists and Social Workers, American Congress of Rehabilitation Medicine, American Occupational Therapy Association, American Paraplegia Society, American Physical Therapy Association, American Psychological Association, American Spinal Injury Association, Association of Academic Physiatrists, Association of Rehabilitation Nurses, Congress of Neurological Surgeons, Insurance Rehabilitation Study Group, Paralyzed Veterans of America, U.S. Department of Veterans Affairs.

SOURCE(S) OF FUNDING

Administrative and financial support provided by Paralyzed Veterans of America.

GUIDELINE COMMITTEE

Guidelines Development Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of the Committee Members: Jason Mask, LCSW (Chair); Kimberly Arlinghaus, MD; Helen Bosshart, LCSW; Lester Butt, PhD; Rebecca R. Clearman, MD; Mary J. McAweeney, PhD; Barbara Simmons, MSN, RN

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of January 2005, based on a review of literature published since the original guideline publication.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Paralyzed Veterans of America Web site.

Print copies: Available from the Paralyzed Veterans of America, 801 Eighteenth Street, NW, Washington, DC 20006; Web site: www.pva.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Depression: what you should know. A consumer guide for people with spinal cord injury. Washington (DC): Paralyzed Veterans of America, c1999. Available from the Paralyzed Veterans of America (PVA) Web site.

Print copies: Single copies are available from the Consortium for Spinal Cord Medicine, Clinical Practice Guidelines, 801 18th Street, NW, Washington, DC 20006.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on May 31, 1999. The information was verified by the guideline developer as of November 15, 2000. This summary was updated by ECRI on August 15, 2005, following the U.S. Food and Drug Administration advisory on antidepressant medications.

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